

DETAILED ACTION

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Stephen LeBlanc on 27 March 2008.

The application has been amended as follows: Line 7 of claim 9 has been amended from "an opposite side" to --said opposite side--, in order to clarify that the side is the same as the opposite side in an earlier clause.

Allowable Subject Matter

2. The following is an examiner's statement of reasons for allowance:

The prior art of record fails to anticipate or make obvious the invention of claims 1, 3, 7, 9, and 38, including, *inter-alia*, monitoring glucose disorders by fixing a substance that measures glucose levels on the non-needle side of a dialysis membrane that is in contact with a plurality of out-of-plane microneedles, where the fixing is performed by placing a polymer-detecting substance solution on the membrane after the microneedles have been fabricated and/or assembled, applying the plurality of microneedles to the skin of a subject, where the membrane remains outside the skin, and performing continuous glucose monitoring by testing the composition of a dialysis

fluid that remains outside the skin and is separated from the microneedles by the dialysis membrane.

Gonnelli (US Patent Application Publication 2003/0135158) discloses obtaining fluids from a subject's skin using a group of microneedles (elements 112) and a membrane located on the non-inserted side of the microneedles (element 140, figure 1B). Gonnelli does not disclose performing glucose monitoring, nor fixing a glucose-measuring substance on the membrane.

Sage (US Patent Application Publication 2003/0143746) discloses monitoring glucose levels using needles and a dialysis membrane (paragraphs [0028]-[0029]) to perform continuous glucose monitoring by testing the composition of a dialysis fluid that is separated from the needle by the membrane (paragraphs [0017]-[0018], [0031]-[0032]). Sage does not teach using microneedles, the membrane remaining outside the skin during use, nor fixing a glucose-measuring substance to the membrane.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAREN E. TOTH whose telephone number is (571)272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/
Primary Examiner, Art Unit 3735

/K. E. T./
Examiner, Art Unit 3735